Alert Marketing, Inc. submits the following comments in response to the FDA's guidance document entitled "Using Electronic Means to Distribute Certain Product Information" (the "Guide"):

In the Guide, the FDA clarifies that "voluntary recall communications for FDA-regulated products and/or important drug safety information" may be sent by electronic means, including e-mail and facsimile. Although the Guide devotes the most text to voluntary recalls, its repeated references to "other important drug safety information" and to 21 CFR Section 200.5 ("Section 200.5") make clear that the Guide's recommendations apply to a broader range of information. Section 2005, which is called "Mailing of important information about drugs," covers not only information that "concerns a significant hazard to health," which would be a recall, but also information that "concerns important changes in drug package labeling," which would be, for example, a new warning, and information that "concerns a correction of prescription advertising or labeling," which would include a dosage change or a new indication.

The Guide's stated purpose is simply to clarify that such communications need not be sent by direct mail, as 21 CFR Sections 7.49 and 200.5, which were written before the advent of the Internet, might be interpreted to require. But the Guide goes further than that. The Guide makes a strong argument that sending out such information by electronic means, including faxing, is the *only* way to ensure that the majority of doctors and pharmacists who need this information will get it timely. As the Guide states, "Many are now concerned that these important drug information communications sent to physicians and other health care providers are not reaching the intended audience and/or not reaching them in a timely manner. Letters to health care professionals often are first seen by one or more 'gatekeepers' and may not reach the intended recipients -- the providers who need the drug information for treating patients. Gatekeepers often discard these mailings as 'junk mail.'" This is a serious problem, as the Guide properly notes, because "[t]he timely dissemination of communications about recalls of FDA regulated products, important drug safety information, and other important product safety information is *essential for the protection of the public health*." (Emphasis added.)

For this reason, many pharmaceutical companies long ago began to use facsimile broadcasts, either in place of or in addition to direct mail, to communicate drug safety information. They have found that faxes are more effective than e-mail, especially because e-mails typically get buried in a long stream of unsolicited spam and go unnoticed. But there is one major obstacle: the provisions of the Telephone Consumer Protection Act ("TCPA") of 1991, as interpreted and supplemented by FCC regulations and as recently amended by the Junk Fax Prevention Act of 2005. The TCPA makes it illegal to "use any telephone facsimile machine, computer, or other device to send an unsolicited advertisement to a facsimile machine." The TCPA defines an "unsolicited advertisement" as "any material advertising the commercial availability or quality of any property, goods or services which is transmitted to any person without that person's express invitation or permission." Clearly that term reasonably might be read as encompassing all three categories of information covered by Section 200.5 and a whole range of additional information that may fall under the definition of "important drug

safety information." Anyone found to have violated the TCPA is liable to pay the recipient $500.00 for each unsolicited fax, and up to $1,500.00 per unsolicited fax if the transmission was "intentional." The statute does not define "intentional," and it makes no exception for any particular content.

In addition to authorizing the FCC to take action against companies that violate the TCPA, the TCPA permits individuals to bring private lawsuits for violations of the unsolicited fax provisions. Since the TCPA was passed 14 years ago, there have been tens of thousands of actual and threatened lawsuits alleging violation of the unsolicited fax provisions, including hundreds of class-action lawsuits. Between April 2002 and November 2004, there were over 150 class-action lawsuits in the Chicago area alone (and Chicago is not even one of the "hotbeds" of fax litigation). Countless plaintiffs' lawyers are going around buying unsolicited faxes from recipients in exchange for the right to sue the senders. They routinely claim that the sending of any unsolicited fax was "intentional" by virtue of the mere fact that it was sent, even though this makes no sense and is hardly settled law. The result has been a significant risk to pharmaceutical companies and companies that provide facsimile broadcasting services for them.

Although the Junk Fax Prevention Act, signed into law in July of this year, clarifies that advertising faxes can be sent without "express" permission where there is an "established business relationship" between the sender and the recipient (and an opt out from future faxes is offered), a new California statute scheduled to take effect on January 1, 2006, will eliminate that exception for any faxes sent to or from that state.

The canned response to this complaint is, just get permission. That is much easier said than done. In light of the need to prove the existence of express permission and uncertainty about the scope of the established business relationship exception, many companies involved in fax broadcasting for pharmaceutical companies are slowly compiling their own lists of "express consents," but the fact is that most pharmaceutical companies, especially those that rely on fax broadcasters to conduct their information campaigns for them, do not have their own lists of doctors and pharmacists who have expressly consented to receive faxes about their products. Indeed, no comprehensive list of all doctors and pharmacists who have consented to receive such faxes exists. Just about any pharmaceutical company that wants to get important drug safety information out to tens of thousands of doctors and pharmacists will have to hire a fax broadcaster, and that fax broadcaster is going to have to rent a list of names that almost certainly include doctors and pharmacists who have not consented to receive such faxes.

Given how long it is taking and will take for tens of thousands of them to provide their express consent to many different companies, at least for the moment, it is inevitable that many if not most of the doctors and pharmacists on any list will not yet have consented in writing. As a result of the ever-growing litigation, even the American Medical Association now refuses to guarantee that names on its lists have consented to receive faxes. Unless and until every single doctor and pharmacist who might need important drug safety information has given his or her express consent, the fact is that every time a pharmaceutical company sends, or has a fax broadcaster send, a fax with

such information, that company risks getting sued (as does the fax broadcaster in many situations). And while each individual plaintiff may seek "only" $1,500.00 per fax, the only limit on the number of claims that can be made on the basis of any one fax sent to multiple recipients is the number of recipients. At $1,500 per recipient, that limit can literally bankrupt the sender.

When one considers the evident need for doctors and pharmacists to receive certain "important drug safety information" as quickly as possible and in a manner that will get their prompt attention, as the FDA recognizes in the Guide, it makes no sense for federal law to subject pharmaceutical companies and their fax agents to the risk of ruinous litigation in return for their efforts to disseminate such information. Ideally, the TCPA itself should be changed to exempt such communications from the definition of "advertisement" altogether, which would remove this kind of communication from the prohibited category of "unsolicited advertisement." Another option would be to provide that it shall be a defense to a complaint filed pursuant the statute that the "unsolicited advertisement" at issue was a communication concerning important drug information. Since a defense would put the burden of proof on the defendant, this kind of change would offer less protection to pharmaceutical companies who need to send out recalls and other drug safety information as quickly as possible, but it would put them in a better position than the position they are in now under the current law.

Given how long and how difficult it most likely would be to effect yet another change in the law itself, the next best action would be a modification or clarification of the regulations that would have the same effect. In a 1992 TCPA rulemaking order, the FCC stated that the TCPA gives the FCC no discretion "to create exemptions from or limit the effects of the prohibition [against faxing unsolicited advertisements]." But the FCC does have the authority to interpret a statutory term, which it exercised, for example, in interpreting "invitation or permission" to include an existing business relationship. The FCC also has the authority to clarify the nature and scope of the statute's application based on an examination of the real-world circumstances that exist in situations where the law comes into play, as it did in distinguishing between the "senders" of faxes and "fax broadcasters." It would seem to be a logical extension of the FCC's authority as demonstrated by these changes for the FCC to clarify that a drug safety communication, and communications concerning dosages, side effects, etc., are not "advertisements" within the statutory sense of the word. At a minimum, the inconsistency between the TCPA and the implementing regulations as they currently exist, and the FDA's strong recommendation that pharmaceutical companies use electronic means, including faxes, to circulate important drug safety information in a timely way, should be acknowledged and reviewed. A coherent policy that recognized and eliminated this inconsistency between the law and the realities of this situation would benefit not just the pharmaceutical companies but the doctors and pharmacists who need this information -- and, most important, the patients who stand to suffer without it.

On August 25, 2003, in a rulemaking proceeding now pending at the FCC (GC Docket No. 02-278), Alert Marketing's parent company, Jobson Publishing L.L.C., attempted to obtain a similar result by filing a timely request for clarification of newly

announced fax (and telemarketing) rules that had been issued in July 2003. That request asked the FCC to clarify that a fax containing information about a drug's safety, dosages, or side effects, about the FDA's approval of a drug, or about a change in a drug's National Drug Code (NDC), is not an "advertisement" under the TCPA. Jobson's position was summarized in that filing as follows:

> These communications, which employ a variety of media—including faxes—can be said in one sense to be making known the commercial availability of products and services, but they are much more than that. They are intended and, more importantly, received as educational and informational material that is crucial to the maintenance of high quality health care in the United States and beyond. If the regulations enacted by the Commission expose Jobson to massive liability for sending this type of information by fax, its business will suffer, communication of crucial medical information will be restricted and the quality of healthcare for Americans will be diminished.

More than two years later, the FCC has not ruled on this request, or any of the others submitted to it. The FDA could provide a meaningful public service by advising the FCC that at a minimum, the faxing of important drug safety information as defined in the Guide to pharmacists and doctors is crucial to the health of the nation, and by recommending that the FCC clarify in its pending rulemaking that faxes containing such information are not advertisements under the TCPA.

Dave Leyden, President
Jessica R. Friedman, General Counsel